IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF SOUTH CAROLINA
COLUMBIA DIVISION

United States of America, *ex rel.* [FILED UNDER SEAL], Plaintiff-Relator, v. [FILED UNDER SEAL], Defendant.	Civ. A. No. 3:17-2945-JFA COMPLAINT (Jury Trial Demanded) (False Claims Act, 31 U.S.C. §§ 3729-3733) **DO NOT PLACE IN PRESS BOX** **DO NOT ENTER ON PACER**

FILED *IN CAMERA* AND UNDER SEAL
PURSUANT TO 31 U.S.C. § 3730(b)(2)

This *qui tam* action is brought by [FILED UNDER SEAL], an individual, on behalf of the United States of America ("United States" or "Government"), against [FILED UNDER SEAL] for treble damages and civil penalties arising from [FILED UNDER SEAL] unlawful scheme to defraud the United States' Medicare program by knowingly submitting false or fraudulent claims for reimbursement in violation of the False Claims Act, as amended, 31 U.S.C. §§ 3729 *et seq.* (the "FCA").

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF SOUTH CAROLINA
COLUMBIA DIVISION

United States of America, *ex rel.* Elaine Jeter, M.D., Plaintiff-Relator, v. Myriad Genetics, Inc., Defendant.	Civ. A. No. 3:17-2945-JFA COMPLAINT (Jury Trial Demanded) (False Claims Act, 31 U.S.C. §§ 3729-3733) **DO NOT PLACE IN PRESS BOX** **DO NOT ENTER ON PACER**

FILED *IN CAMERA* AND UNDER SEAL
PURSUANT TO 31 U.S.C. § 3730(b)(2)

This *qui tam* action is brought by Plaintiff-Relator Dr. Elaine Jeter, M.D. ("Dr. Jeter" or "Relator"), an individual, on behalf of the United States of America ("United States" or "Government"), against Defendant Myriad Genetics, Inc. ("Myriad") for treble damages and civil penalties arising from Myriad's unlawful scheme to defraud the United States' Medicare program by knowingly submitting false or fraudulent claims for reimbursement in violation of the False Claims Act, as amended, 31 U.S.C. §§ 3729 *et seq.* (the "FCA").

INTRODUCTION

1. Myriad's fraudulent scheme is simple—it routinely falsifies test and procedure codes on Medicare claim forms in order to get reimbursed at a higher rate than Medicare allows for its myRisk® Hereditary Cancer test. Specifically, Myriad bills Medicare using legacy test and procedure codes that do not apply to myRisk® to get paid at the rate Medicare allows for those codes (approx. $2700) instead of the rate Medicare has approved for myRisk® ($925). By doing so, Myriad has illegally profited tens of millions of dollars at the Government's expense.

2. Myriad has routinely violated the FCA by submitting false claims to Medicare for legacy tests that it did not perform, and by creating false or fraudulent records material to those false claims. Plus, having knowingly submitted false claims to Medicare for payment, Myriad has also violated the FCA by failing to return overpayments for illegally obtained federal funds.

3. As required by the FCA, Dr. Jeter is providing the Attorney General of the United States and the United States Attorney for the District of South Carolina with a statement of all material evidence and information related to this Complaint. This disclosure statement is supported by material evidence known to Dr. Jeter at the time of the filing of this Complaint that establishes the deliberate submission of false claims by Myriad to the Government.

JURISDICTION AND VENUE

4. This action arises under the laws of the United States of America to redress violations of the FCA. Thus, this Court has subject-matter jurisdiction over this *qui tam* action pursuant to 28 U.S.C. §§ 1331 and 1345, and 31 U.S.C. §§ 3732(a) and 3730(b). Dr. Jeter is not aware of any other complaints filed against Myriad that make the same or similar allegations, or of any public disclosure of the allegations and information contained in this Complaint. Therefore, she is an original source as defined by the FCA and as described more fully herein.

5. This Court has personal jurisdiction over Myriad because Myriad does business in the United States, including in South Carolina. Specifically, personal jurisdiction is proper because (1) nationwide service of process is authorized by 31 U.S.C. § 3732(a), and (2) Myriad has sufficient minimum contacts with the United States as a whole, and South Carolina in particular, including that Myriad can be found in, transacts, or has transacted business in this State, contracts to supply services or things in this State, and enters into contracts to be performed in whole or in part by either party in this State.

6. This Court is a proper venue for this *qui tam* action under 28 U.S.C. § 1391(b) and 31 U.S.C. § 3732(a), because a substantial part of the events or omissions giving rise to these claims occurred here and because Myriad regularly transacts business in the District of South Carolina.

***IN CAMERA* REVIEW**

7. Pursuant to 31 U.S.C. § 3730(b)(2), this Complaint is to be filed *in camera* and is to remain under seal for a period of at least 60 days and shall not be served on Myriad until this Court so orders.

THE PARTIES

Plaintiff-Relator Dr. Elaine Jeter, M.D.

8. Plaintiff-Relator Dr. Elaine Jeter, M.D., is a citizen of the United States of America and the State of South Carolina. Dr. Jeter is suing Defendant Myriad Genetics, Inc., in the name of, and on behalf of, the United States of America. Dr. Jeter brings this action based upon her direct, independent, and personal knowledge of the facts alleged herein, and based upon other information and belief.

9. Dr. Jeter is a Medical Director for Palmetto GBA ("Palmetto"), a Medicare Administrative Contractor ("MAC") headquartered in Columbia, South Carolina that administers Medicare health insurance claims for the Centers for Medicare & Medicaid Services ("CMS"). Palmetto is one of the nation's largest providers of high-volume claims processing for the Government and other commercial customers. Beginning in November 2011, Dr. Jeter founded and directed Palmetto's Molecular Diagnostic Services Program ("MolDX").

10. Dr. Jeter is a board-certified pathologist in anatomic and clinical pathology, with subspecialty boards in blood banking and transfusion medicine. Dr. Jeter practiced surgical pathology and directed clinical laboratories in academia and the private sector prior to her medical directorship at Palmetto.

Defendant Myriad Genetics, Inc.

11. Defendant Myriad Genetics, Inc. is a molecular diagnostic testing company that was founded in May 1991 and is headquartered in Salt Lake City, Utah. Among other products, Myriad developed the myRisk® Hereditary Cancer panel, a Molecular Diagnostic Test ("MDT") that it markets and sells to the medical industry, including doctors, patients, health insurers, and other medical professionals. Myriad's current President and CEO is Mark C. Capone.

FACTUAL BACKGROUND

Myriad's Hereditary Breast Cancer Tests

12. Prior to the United States Supreme Court's decision in *Association for Molecular Pathology v. Myriad Genetics, Inc.*, 133 S. Ct. 2107 (2013), which held that isolated gene sequences are ineligible for patenting, Myriad was the sole provider of hereditary cancer tests used to identify individuals who carry a *BRCA1* or *BRCA2* gene mutation.

13. It is believed that approximately 7% of breast cancer cases and 11-15% of ovarian cancer cases are caused by an inherited mutation in the *BRCA1* or *BRCA2* genes, which carries with it an up to 87% risk of developing breast cancer and up to 40% chance of developing ovarian cancer.

14. From 1996 through 2013, Myriad performed over one million BRCA tests and collected more than $2.8 billion in revenue through sales of its BRAC*Analysis*® tests. To corner the market for BRCA testing, Myriad acquired broad patents to the *BRCA1* and *BRCA2* genes in 1997 and 1998, respectively, and refused to license its BRAC*Analysis*® test to any other laboratories in the U.S. after bringing it to market in 1996.

15. Nine laboratories that provided *BRCA1* and *BRCA2* testing before Myriad acquired its patents subsequently withdrew from the U.S. market, and no one challenged Myriad's patents for more than a decade. Thus, from 1996 through mid-2013, Myriad enjoyed a monopoly (100% market share) on MDTs used to identify individuals who carry a *BRCA1* or *BRCA2* gene mutation.

16. Myriad's BRAC*Analysis*® test, introduced in 1996, utilized traditional Sanger sequencing technology to detect the presence of single-based changes (small deletions/insertions), which are common mutations in the *BRCA1* and *BRCA2* genes.

17. In August 2002, Myriad enhanced its BRAC*Analysis*® test to include the detection of five common, large rearrangements (duplications/deletions) that were also discovered to negatively affect gene function, and it re-named the test "Comprehensive BRAC*Analysis*®."

18. In August 2006, Myriad introduced a companion test, the BRAC*Analysis*® Rearrangement Test ("BART"), which it used to detect uncommon, large rearrangements (duplications/deletions) in *BRCA1* and *BRCA2* that were not detected through Comprehensive BRAC*Analysis*®.

19. In 2012, Myriad began marketing a combination of Comprehensive BRAC*Analysis*® and BART under a single product offering it called "Integrated BRAC*Analysis*®."

20. From 1996 through 2013, BRAC*Analysis*® (under its various iterations) was Myriad's major revenue producer, accounting for over 75% of the company's total revenues. For example, during the second quarter of 2013 alone, the company recorded $115.4 million in revenues from BRAC*Analysis*® compared to $156.5 million in total revenues, the latter of which increased 21% from 2012.

21. Amid legal challenges to Myriad's patents and fear that it would lose its monopoly on BRCA testing, Myriad announced in May 2013 that it would launch a new multi-hereditary cancer panel by the end of 2013—to be called the myRisk® Hereditary Cancer panel—that would replace Integrated BRAC*Analysis*® and Myriad's other "a la carte" BRCA cancer tests, which would all be phased out by the end of 2015.

22. In its announcement, Myriad stated that myRisk® would include an analysis of 25 genes that it claimed were "clinically actionable," several of which were protected by Myriad's patents at that time, and all of which would be analyzed using Next Generation Sequencing ("NGS") technology instead of traditional Sanger sequencing.

23. Less than two months after Myriad unveiled its new myRisk® panel, the Supreme Court invalidated Myriad's patents on the *BRCA1* and *BRCA2* genes, and Myriad lost its monopoly on BRCA testing. Shortly thereafter, competing laboratories began offering BRCA testing utilizing traditional Sanger sequencing for as little as a few hundred dollars, a small fraction of the roughly $4,000 Myriad charged for Integrated BRAC*Analysis*®.

24. Likewise, in December 2013 a competing laboratory, InVitae Corporation, announced that it would offer a competing hereditary breast cancer-related panel utilizing NGS for approximately one-third of Myriad's $4,500 list price for myRisk®.

MEDICARE AND MolDX

The Medicare Program

25. The Health Insurance for the Aged and Disabled Act (Title XVIII of the Social Security Act), 42 U.S.C. §§ 1395 *et seq.*, commonly known as Medicare, is a health insurance program designed to assist the nation's elderly meet their healthcare costs. Medicare also provides coverage for younger individuals who are permanently disabled.

26. Among other benefits, Medicare includes hospital insurance under Part A, and supplemental medical insurance ("SMI") under Part B. Medicare Part B, 42 U.S.C. §§ 1395c-1395w-6, is a voluntary medical insurance plan designed to supplement hospital insurance coverage. Part B is financed by premiums paid monthly by enrollees which are subsidized by the Government.

27. Generally, Medicare Part B provides coverage for items or services that: (1) fall within a defined Medicare benefit category; (2) are not excluded from coverage by statute, regulation, National Coverage Determination ("NCD"), or Local Coverage Determination ("LCD"); and (3) are determined to be reasonable and necessary for the treatment of an illness or injury.

28. Specifically, Medicare Part B provides coverage for "medical and other health services." 42 U.S.C. § 1395l(a)(1). Section 1395x(s)(3) defines "medical and other health services" to include "diagnostic laboratory tests." Section 1395y(a)(1)(A), however, excludes

from coverage any item or service which is not "reasonable and necessary for the diagnosis or treatment of illness or injury."

29. The majority of laboratory testing is paid for by Medicare on a fee-for-service basis. Under 42 U.S.C. § 1395l, outpatient clinical laboratory services are reimbursed by Medicare based upon a fee schedule, known as the Clinical Laboratory Fee Schedule ("CLFS").

30. Clinical laboratories submit claims for payment to the Government health programs directly, including Medicare.

31. A clinical laboratory must accept assignment of the Medicare beneficiary's benefit in order to receive Part B payment for laboratory tests based on the CLFS. *See* Medicare Claims Processing Manual, Chapter 16 – Laboratory Services, Section 30.1 – Mandatory Assignment for Laboratory Tests. Thus, Part B deductible and coinsurance (co-payments) do not apply to laboratory services provided by a physician or an independent laboratory. *Id.* Section 30.3 – Method of Payment for Clinical Laboratory Tests – Place of Service Variation.

32. The laboratory that submits the claim to Medicare must also maintain any documentation it receives from the ordering physician, as well as documentation that the information the lab submitted with the claim accurately reflects the information it received from the ordering physician or non-physician practitioner. 42 C.F.R. § 410.32(d)(2)(ii).

33. To administer parts of the Medicare program, including Part B, CMS relies on a network of MACs that intermediate between CMS and the health care providers that are enrolled in the program. Currently, CMS contracts with nine different MACs, which have been awarded contracts for one or more geographic jurisdictions.

34. Among other services, MACs process Medicare claims, make and account for Medicare payments, enroll providers in the Medicare program, respond to provider inquiries,

educate providers about Medicare billing requirements, and establish coverage (or non-coverage) for items or services through LCDs.

35. CMS has broad authority to outline conditions and limitations on whether an item or service will be covered by Medicare nationally through the issuance of a NCD. *See* 42 U.S.C. § 1395ff(f)(1)(B) (defining "national coverage determination" as "a determination by the Secretary with respect to whether or not a particular item or service is covered nationally under this title….").

36. Locally, MACs have the authority to outline "reasonable and necessary" conditions and limitations on whether an item or service will be covered by Medicare in its jurisdiction through the issuance of a LCD. *See* 42 U.S.C. § 1395ff(f)(2)(B) (defining "local coverage determination" as "a determination by a fiscal intermediary…respecting whether or not a particular item or service is covered on an intermediary–or carrier–wide basis under such parts, in accordance with section 1862(a)(1)(A).").

37. Pursuant to 42 U.S.C. § 1395y(a)(1(A), a LCD is an authoritative determination of whether an item or service is "reasonable and necessary" for purposes of coverage and reimbursement in that particular jurisdiction.

The MolDX Program

38. During her time as Medical Director at Palmetto, Dr. Jeter founded and directed the MolDX program. CMS began funding MolDX in 2011 at Dr. Jeter's request so that Palmetto could: (1) implement a system to uniquely identify each MDT[1] for which Medicare coverage existed, or would be sought, in Palmetto's jurisdictions; (2) conduct a technical assessment on new

[1] An MDT is defined by MolDX as "[a] test that involves the detection or identification of nucleic acids (DNA/RNA), proteins, chromosomes, enzymes, cancer chemotherapy sensitivity and/or other metabolites. The test may or may not include multiple components. An MDT may consist of a single mutation analysis/identification, and/or may or may not rely upon an algorithm or other form of data evaluation/derivation." MolDX: Coverage, Coding, and Pricing Standards and Requirements, at 3, Version 13.0 October 2017, located at https://www.palmettogba.com/Palmetto/moldx.Nsf/files/MolDX_Manual.pdf/$File/MolDX_Manual.pdf?Open&.

MDTs, and those for which clinical and analytical validity and clinical utility had not been proven, to determine whether Medicare's coverage requirements were met;[2] and (3) establish a new policy whereby all MDTs brought to market are deemed non-covered until registered and MolDX has performed a technical assessment and made a determination of coverage.

39. MolDX's policy, whereby all new MDTs brought to market are deemed non-covered until registered and subjected to a technical analysis, was implemented because the evidentiary threshold needed for new MDTs to gain regulatory clearance and enter the marketplace is considerably lower than the threshold payors require to extend coverage and set reimbursement levels. Thus, demand for new MDTs, including NGS panels such as Myriad's myRisk®, often precedes proof of clinical utility.

40. The MolDX program has since been incorporated into contracts with three other MACs, and its requirements now apply to any provider that conducts MDTs and seeks coverage and reimbursement in the following Medicare jurisdictions: (1) Jurisdiction M (JM), which is administered by Palmetto and includes NC, SC, VA, and WV; (2) Jurisdiction E (JE), which is administered by Noridian Healthcare Solutions ("Noridian") and includes CA, NV, and HI;[3] (3) Jurisdiction F (JF), which is administered by Noridian and includes AK, AZ, ID, MT, ND, OR, SD, UT, WA, and WY; (4) Jurisdiction 15 (J15), which is administered by CGS Administrators and includes KY and OH; (5) Jurisdiction 5 (J5), which is administered by WPS Government Health Administrators ("WPS") and includes IA, KS, MO, and NE; and (6) Jurisdiction 8 (J8), which is administered by WPS and includes IN and MI.[4]

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[2] MolDX's program requirements state that "MolDX only provides coverage for MDTs…that demonstrate analytical validity, clinical validity, and clinical utility." *Id.* at 6.

[3] JE also includes the U.S. Pacific Territories of Guam, American Samoa, and the Northern Marianas.

[4] For an up-to-date map of all current MACs by geographic jurisdiction *see* https://www.cms.gov/Medicare/Medicare-Contracting/Medicare-Administrative-Contractors/Who-are-the-MACs.html#MapsandLists.

41. Under MolDX's requirements, to obtain coverage for new or established MDTs, providers must first register the test and obtain a unique Diagnostic Exchange ("DEX") z-code identifier from McKesson.[5]

42. For newly developed tests, and for established tests that have not been validated for clinical and analytical validity and clinical utility, laboratories must then submit a detailed dossier of clinical data to MolDX demonstrating that the test meets Medicare's "reasonable and necessary" coverage requirements. All new tests are deemed non-covered by Medicare until MolDX has reviewed the clinical data and determined that the test is "reasonable and necessary."

Coding and Reimbursement for MDTs

43. As described above, reimbursement for clinical laboratory services under Medicare Part B is based upon the CLFS. The CLFS incorporates the Health Care Common Procedure Coding System ("HCPCS"), which is the medical billing process CMS requires that providers use to bill Medicare.

44. The HCPCS provides a standard coding system to describe the specific items and services provided in the delivery of health care. Standardized coding is necessary for Medicare and other health insurance programs to ensure that insurance claims are processed in an orderly and consistent manner.

45. The HCPCS is divided into two principal subsystems, referred to as Level I and Level II codes. Level I codes include Common Procedure Technology ("CPT®") codes, which is a uniform coding system of descriptive terms and identifying codes used to categorize medical services and procedures provided by physicians and other health care professionals.

[5] MolDX partners with McKesson via the DEX for test registration.

46. The American Medical Association ("AMA") establishes CPT® codes, which are in turn used by public and private payors under licensing agreements. Today, the AMA CPT® coding system has been adopted by virtually all health insurers, including Medicare.

47. The AMA categorizes CPT® codes into a series of related codes. CPT® codes in the 80000 – 89999 range describe clinical laboratory services.

48. Prior to January 2013, test providers billed for MDTs using various combinations of CPT® methodology codes (83890 – 83914), with each code describing an individual component of the test being performed. This billing method became known as "stacking" because several codes were layered on top of one another to describe the individual steps taken to perform a test.

49. Stacking created numerous problems for payors, including that (1) the same MDT was billed using many different combinations of codes, and (2) different MDTs were billed using the same combination of codes. This lack of transparency to payors as to exactly which test was being performed was an impetus for the MolDX program being instituted by CMS in 2011, and for analyte-specific Tier 1 (T1) and Tier 2 (T2) Molecular Pathology ("MoPath") codes being established by AMA in 2012 and implemented by CMS in January 2013.[6]

50. T1 MoPath codes describe commonly performed, simple analyte MDTs. T2 codes describe more complex, less frequently performed MDTs.[7]

51. When the MoPath codes were developed in 2012, the vast majority of laboratories were using polymerase chain reaction and other non-NGS analyses to interrogate a single gene or

[6] Because they describe molecular diagnostic testing services using analyte-specific terminology, the T1 (81161-81355) and T2 (81400-81408) MoPath codes are subject to the unique coverage, coding, and pricing decisions of MolDX.

[7] T2 codes include an "unlisted" code, 81479, which MDT providers used to bill for NGS panels prior to 2016.

gene component. Therefore, the MoPath codes only describe services for a single (or occasionally two) gene test.

52. Unlike the tests described by the T1 and T2 MoPath codes, NGS panels target and detect multiple specific genes of interest, including common variants, duplication/deletion variants, and known familial variants in one "run" to create a single report. As such, MolDX considers a NGS panel to be a single test with multiple potential indications, and has issued guidance to that effect.

53. Thus, MolDX prohibits test providers from billing for NGS panels under T1 or T2 MoPath codes even if a single gene or multiple genes are selected for NGS testing. Specifically, MolDX has informed test providers, including Myriad, that it will deny reimbursement of any NGS panel billed with T1 and/or T2 codes as an improperly unbundled service from the primary NGS panel.

54. MolDX has instructed test providers to instead bill for NGS panels by comparing the CPT® code descriptions in the new Genomic Sequencing Procedure and Other Molecular Multianalyte Assay ("GSP") section, which was implemented by CMS in January 2016, and selecting the code that best describes the test performed.

55. Specifically, MolDX instructed test providers to only use the following CPT® GSP codes to bill for NGS panels on or after January 1, 2016: 81410, 81412, 81415, 81417, 81420, 81425, 81430, 81432, 81433, 81434, 81435, 81437, 81440, 81442, 81445, 81450, 81455, 81460, 81465, and 81470.

56. Regardless of the technology utilized, MolDX requires test providers that perform MDTs in a MolDX jurisdiction to bill Medicare by listing: (1) the CPT® code that best describes the test performed, and (2) the test's unique DEX z-code. When reported in conjunction with the

appropriate CPT® code, the DEX z-code allows MACs to determine the exact test that was performed, which facilitates claims processing and informs pricing and coverage decisions.

57. In MolDX jurisdictions, claims submitted for MDTs are not paid unless the test's unique DEX z-code is listed on the claim form and corresponds with the proper CPT® code. Thus, if a test provider fails to identify the MDT it performed by listing the DEX z-code in a designated field on the Medicare claim form, the claim will be denied. Similarly, if the DEX z-code listed on the claim form does not correspond with the proper CPT® code, the claim will be denied.

BRAC*Analysis*® and myRisk®

Medicare Coverage, Coding, and Reimbursement

58. In 2015, Palmetto issued LCD L36082 titled "MolDX: BRCA1 and BRCA2 Genetic Testing" that governs *BRCA1* and *BRAC2* genetic testing performed on or after October 5, 2015, and specifies the conditions and limitations under which such testing will be covered by Medicare. LCD L36082 governs any *BRCA1* or *BRCA2* test performed in a Medicare jurisdiction where MolDX applies, including in JF where Myriad is headquartered.

59. Pursuant to MolDX policy, Myriad applied for and received unique DEX z-codes for each of its Comprehensive BRAC*Analysis*®, Integrated BRAC*Analysis*®, BART, and myRisk® hereditary cancer tests.

60. MolDX has determined that Myriad's Comprehensive BRAC*Analysis*®, BART, Integrated BRAC*Analysis*®, and myRisk® tests all satisfy the conditions and limitations set forth in LCD L36082 and, therefore, meet Medicare's "reasonable and necessary" requirements for a covered service.

61. MolDX has instructed Myriad on the proper CPT® codes under which to bill Medicare for its legacy BRCA tests. Specifically, MolDX has instructed Myriad to bill for

Comprehensive BRAC*Analysis*® under CPT® code 81211, BART under 81213, and Integrated BRAC*Analysis*® under 81162. Medicare reimbursement rates for legacy tests billed under these codes is around $2200, $500, and $2500, respectively.

62. During a technical assessment of Myriad's new myRisk® panel in October 2015, MolDX learned that AMA would release new GSP codes in late 2015 that describe NGS panels, including a code that specifically describes myRisk®. As a result, MolDX terminated its assessment of myRisk® because (1) the myRisk® panel included the interrogation of several genes that already had proven medical utility, and (2) effective January 1, 2016, there would be an appropriate CPT® code under which Myriad could bill Medicare for myRisk®.

63. In the interim (September 2015 – January 2016), MolDX instructed Myriad to bill Medicare for myRisk® using the test's unique DEX z-code and CPT® code 81479, a Not Otherwise Classified ("NOC") code that was used to bill for NGS panels prior to the new GSP codes being implemented in 2016. CMS set interim reimbursement for breast cancer-related NGS panels billed under 81479 at the sum of codes 81211 and 81213 (approximately $2700).

64. After the new GSP codes were implemented by CMS on January 1, 2016, MolDX instructed Myriad to bill Medicare for myRisk® using (1) the unique DEX z-code assigned to myRisk®, and (2) new CPT® code 81432 because it best described the myRisk® panel.

65. To establish reimbursement rates for new tests that are assigned new CPT® codes, CMS regulations require that one of two processes be used: (1) crosswalking, or (2) gapfilling. *See* 42 C.F.R § 414.508. Crosswalking is used if CMS determines that the new test is comparable to an existing test, multiple existing test codes, or a portion of an existing test code. If CMS finds that an existing test or code(s) are comparable, the price for the new code is established by

crosswalking (or linking) it to the comparable code(s). If, however, CMS finds that no comparable test or code(s) exists, gapfilling is used to determine the payment amount.

66. Because no existing test or code(s) was found to be comparable to myRisk®, CMS determined that pricing for CPT® code 81432 would be gapfilled. Pursuant to the gapfilling process described in 42 C.F.R § 414.508(a)(2)(i), and despite pushback from Myriad and other industry insiders, the interim reimbursement rate for 81432 was set at $622 based upon (1) the average number of genes that had proven medical utility for breast, colon, melanoma, gastric, and lung cancer, and (2) the large reduction in sequencing costs that accompanies NGS. After a brief public comment period, CMS set the final reimbursement rate for 81432 at $925.

67. As a result of CMS setting the final reimbursement rate for CPT® code 81432 at $925, NGS panels billed under 81432 are reimbursed by Medicare at a substantially lower rate than legacy BRCA tests billed under a combination of codes 81211 and 81213 (approximately $2700), or the same tests billed under 81162 (approximately $2500), which was established in 2016 to describe a composite of codes 81211 and 81213.

Myriad's Fraudulent Billing Practices

68. Before MoPath codes were established by the AMA in 2012, and implemented by CMS in January 2013, Myriad billed Medicare for its legacy BRAC*Analysis*® tests, including BRAC*Analysis*®, Comprehensive BRAC*Analysis*®, BART, and Integrated BRAC*Analysis*®, by stacking various CPT® methodology codes (83890 – 83914) on top of one another.

69. After MoPath codes were implemented by CMS in January 2013, Myriad began billing Medicare for Comprehensive BRAC*Analysis*® using T1 code 81211, BART using T1 code 81213, and Integrated BRAC*Analysis*® using a combination of codes 81211 and 81213.

70. After myRisk® was brought to market in 2013, Myriad began billing Medicare for myRisk® using a combination of CPT® codes 81211 and 81213. This combination resulted in a total reimbursement from Medicare of approximately $2700 for each myRisk® panel.

71. To increase sales of myRisk®, Myriad discontinued all of its legacy BRCA tests by the end of 2015. Since 2015, Myriad has not allowed doctors or other medical professionals to order its legacy BRCA tests (Comprehensive BRAC*Analysis*®, BART, or Integrated BRAC*Analysis*®). Instead, Myriad has limited its *BRCA1* and *BRCA2* hereditary cancer testing to sales and performance of its myRisk® panel. To do so, Myriad removed the option that allowed physicians to request legacy BRCA testing from its Test Request Form in 2015.

72. After CMS implemented the new GSP codes in January 2016, MolDX instructed Myriad to start billing for the myRisk® panel using CPT® code 81432, which describes a genomic sequence panel analysis of at least 14 genes, including *ATM*, *BRCA1*, *BRIP1*, *CHD1*, *MLH1*, *MSH2*, *MSH6*, *NBN*, *PALB2*, *PTEN*, *RAD51C*, *STK11*, and *TP53*, for the evaluation of hereditary breast cancer-related disorders.

73. MolDX instructed Myriad to bill for myRisk® under CPT® code 81432 because the myRisk® panel includes the sequencing and analysis of 14 or more genes, including *ATM*, *BRCA1*, *BRIP1*, *CHD1*, *MLH1*, *MSH2*, *MSH6*, *NBN*, *PALB2*, *PTEN*, *RAD51C*, *STK11* and *TP53*, for the evaluation of hereditary breast cancer-related disorders. Accordingly, MolDX determined that 81432 best describes the services Myriad performs in the myRisk® panel.

74. Despite MolDX specifically instructing Myriad to bill for myRisk® using CPT® code 81432 beginning in January 2016, and explicit guidance from MolDX to stop using legacy T1 codes to bill for NGS panels, Myriad has continued to bill Medicare for myRisk® using legacy T1 and/or T2 MoPath codes.

75. Specifically, Myriad continues to bill Medicare for myRisk® using DEX z-codes for its legacy BRCA tests and T1 and/or T2 MoPath codes that do not best describe the services Myriad performs in the myRisk® panel. Instead of billing Medicare for myRisk® under CPT® code 81432, as Myriad was instructed by MolDX to do, Myriad continues to bill Medicare for myRisk® by reporting either: (1) a combination of codes 81211 and 81213, or (2) code 81162.

76. Myriad continues to bill Medicare for myRisk® using T1 and/or T2 MoPath codes and DEX z-codes for its legacy BRCA tests, despite discontinuing those tests in 2015, because the reimbursement rate associated with those codes (either $2500 or $2700 depending on the code(s) billed) is almost three times the reimbursement rate CMS has approved for hereditary breast cancer-related NGS panels billed under CPT® code 81432 ($925).

77. Thus, to fraudulently obtain almost three times the reimbursement rate that CMS has approved for hereditary breast cancer-related panels billed under CPT® code 81432, Myriad has knowingly and routinely falsified on Medicare claims forms (1) the CPT® code that Myriad was instructed by MolDX to use for myRisk®, and (2) myRisk®'s unique DEX z-code identifier.

78. Indeed, despite Myriad conducting tens of thousands of myRisk® panels for Medicare patients during 2016 and 2017, Myriad has not billed Medicare using CPT® code 81432 at all during those years.

79. Instead, Myriad has fraudulently billed Medicare tens of millions of dollars for thousands of legacy BRCA tests (Comprehensive BRAC*Analysis*®, BART, and/or Integrated BRAC*Analysis*®) that it did not perform in 2016 and 2017 by listing CPT® codes and DEX z-codes for Myriad's legacy BRCA tests on Medicare claim forms despite discontinuing those tests in 2015.

THE FALSE CLAIMS ACT

80. The False Claims Act, in relevant part, provides that:

> any person who (A) knowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval; (B) knowingly makes, uses, or causes to be made or used, a false record or statement material to a false or fraudulent claim; (C) conspires to commit a violation of subparagraph (A), (B), (C) . . . or (G); . . . or (G) knowingly makes, uses, or causes to be made or used, a false record or statement material to an obligation to pay or transmit money or property to the Government, or knowingly conceals or knowingly and improperly avoids or decreases an obligation to pay or transmit money or property to the Government, is liable to the United States Government for a civil penalty of not less than [$10,957] and not more than [$21,916] . . . plus 3 times the amount of damages which the Government sustains because of the act of that person.
>
> * * *
>
> (b) For purposes of this section, the terms the terms "knowing" and "knowingly" (A) mean that a person, with respect to information (i) has actual knowledge of the information; (ii) acts in deliberate ignorance of the truth or falsity of the information; or (iii) acts in reckless disregard of the truth or falsity of the information; and (B) require no proof of specific intent to defraud[.]

31 U.S.C. § 3729(a)-(b) (civil penalties adjusted by the DOJ effective Feb. 3, 2017 pursuant to the Federal Civil Penalties Inflation Adjustment Act of 1990, *see* 28 C.F.R. § 85.5 (2017)).

COUNT 1
False Claims Act, 31 U.S.C. § 3729(a)(1)(A)
Presenting False Claims to Medicare

81. Relator incorporates by reference all preceding paragraphs of this Complaint as if fully set forth herein.

82. Myriad knowingly presented, or caused to be presented, false and fraudulent claims for payment or approval to the United States, including claims for reimbursement identified in this Complaint for laboratory tests that it did not conduct or did not need to conduct.

83. Claims submitted, or that were caused to be submitted, by Myriad for clinical laboratory testing that were not provided, or were useless, constitute violations of the FCA, 31 U.S.C. § 3729(a)(1)(A).

84. Myriad presented these false claims to Medicare for reimbursement with actual knowledge of their falsity, or with reckless disregard or deliberate ignorance of whether or not they were false.

85. By virtue of the false and fraudulent claims made by Myriad, the United States has suffered damages and is therefore entitled to recovery of actual damages in an amount to be determined at trial, treble damages, plus a civil penalty of at least $10,957, but no more than $21,916, for each violation as provided by the False Claims Act. *See* 31 U.S.C. § 3729(a); 28 C.F.R. § 85.5 (2017).

COUNT II
False Claims Act, 31 U.S.C. § 3729(a)(1)(B)
Use of False Statements

86. Relator incorporates by reference all preceding paragraphs of this Complaint as if fully set forth herein.

87. Myriad made, used, and caused to be made or used, false records and statements, *i.e.*, the false certifications and representations made, or caused to be made, by Myriad when initially submitting the false and fraudulent claims for interim payments and the false certifications made by Myriad in submitting the cost reports to get false and fraudulent claims paid and approved by the United States.

88. These false records and statements were made with actual knowledge of their falsity, or with reckless disregard or deliberate ignorance of whether or not they were false.

89. By virtue of the false or fraudulent records and statements made by Myriad, the United States has suffered damages and is therefore entitled to recovery of actual damages in an amount to be determined at trial, treble damages, plus a civil penalty of not less than $10,957, but no more than $21,916, for each violation as provided for by the FCA.

COUNT III
False Claims Act, 31 U.S.C. § 3729(a)(1)(G)
False Record to Avoid an Obligation to Refund

90. Relator incorporates by reference all preceding paragraphs of this Complaint as if fully set forth herein.

91. Myriad made and used, or caused to be made or used, false records or false statements—*i.e.*, the false certifications made, or caused to be made, by Myriad in submitting the cost reports—to conceal, avoid, or decrease an obligation to pay or transmit money or property to the United States.

92. These false records or statements were made with actual knowledge of their falsity, or with reckless disregard or deliberate ignorance of whether or not they were false.

93. By virtue of the false records or false statements presented by Myriad, the United States has suffered damages and is therefore entitled to recovery of actual damages in an amount to be determined at trial, treble damages, plus a civil penalty of not less than $10,957, but no more than $21,916, for each violation as provided for by the FCA.

WHEREFORE, Relator respectfully requests this Court enter judgment against Myriad as follows:

(a) That the United States be awarded damages in the amount of three times the actual damages sustained by the United States by virtue of the false claims alleged within

this Complaint, to the full extent provided for by the False Claims Act, 31 U.S.C. §§ 3729 *et seq.*;

(b) That civil penalties of $21,916 be imposed for each and every false claim that Myriad presented to the United States and/or its grantees;

(c) That pre-judgment and post-judgment interest be awarded, along with reasonable attorneys' fees, costs, and expenses which Relator necessarily incurred in filing and prosecuting this case;

(d) That the Court grant permanent injunctive relief to prevent any recurrence of the False Claims Act violations for which redress is sought in this Complaint;

(e) That Relator be awarded the maximum share allowed to her pursuant to the False Claims Act; and

(f) That this Court award such other and further relief as it deems necessary, just, and proper.

JURY DEMAND

Pursuant to Rule 38 of the Federal Rules of Civil Procedure, Relator hereby demands a trial by jury in this *qui tam* action.

Dated: October 31, 2017

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